

RECEIVED
CENTRAL FAX CENTER
NOV 27 2006

Serial No.: 10/766,139

Docket No.: PVI-5541DIVCON

Amendment After Final dated November 27, 2006

Responsive to the FINAL Office Action dated September 22, 2006

REMARKS

Prior to the present Office Action, claims 18-22, 24-26, and 38-49 were pending. By way of this amendment, Applicant has canceled claims 20 and 40-42, and has added claims 50-57. Therefore, claims 18-19, 21-22, 24-26, 38-39, and 43-57 remain pending.

In the claims, dependent claim 20 has been incorporated into independent claim 18, dependent claim 42 (and preceding claim 40) has been incorporated into independent claim 38, independent claim 44 has been clarified, and new independent claim 50 is essentially a combination of original claims 38 and 43.

Telephonic Interview of November 17, 2006

The undersigned wishes to thank Examiner Miller for a productive telephonic interview on November 17, 2006. The undersigned acknowledges the Examiner's Interview Summary, and generally agrees with the topics discussed. Namely, one subject of discussion was claim 43 which involves axially moving the two valve parts together so that the connectors join. Examiner Miller seemed to understand the difference between that concept and Cribier or Garrison-type valves, where an inner expandable valve part moves axially to within an outer base part and then is radially expanded, but asserted that the language of claim 43 as it stands was yet too broad. However, the Examiner seemed to agree that certain additional structural language concerning the connectors could be introduced to 43 to make it allowable.

The status of Claim 44 relative to Eberhardt was also discussed. Applicants pointed out that Eberhardt is a conventional valve, not involving two parts. The Examiner maintained that the sewing ring of the Eberhardt could be construed as the "tissue-engaging base" element in the claim, and that it "could" be compressed to a collapsed state that fits through a catheter and then expanded. The undersigned disagreed with this interpretation. The undersigned also disagreed that Eberhardt anticipates claim 45, where the base is plastically-expandable. The Examiner stated that sewing ring of Eberhardt could be stretched beyond its limit and torn, and therefore "could" be plastically-expanded.

Serial No.: 10/766,139

Docket No.: PVI-5541DIVCON

Amendment After Final dated November 27, 2006

Responsive to the FINAL Office Action dated September 22, 2006

Claim Rejections - 35 U.S.C. §112

Claims 39, 42-43, 45, and 49 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. In response, Applicant has canceled or amended the claims at issue (or respective base claims) as indicated above, which is believed to address all of these separate items.

Claim Rejections on the Basis of Thorpe, et al.

Claims 38-41 and 44-49 stand rejected under 35 U.S.C. §102(e) as being anticipated by Thorpe et al. (USPN 2003/0130726). Thorpe, et al. disclose a combination valve and stent for treating vascular reflux. The stent is a standard mesh-like tubular structure formed of struts, and the valve is made of sclera or submucosal tissue attached at otherwise undefined "connection sites". The following is an explanation of the intended placement of the device:

It is understood that the optimum location for placement of stent and valve device 43 is generally proximate to existing sites of venous valves in the patient receiving the stent and valve device. However, it is recognized that by using the teachings of this invention it is possible to further optimize and possibly customize a stent and valve device 43 suitable for placement at various locations according to the anatomy of the patient's vein at the specific locations. (Paragraph [0042], lines 7-15)

Applicants respectfully assert that Thorpe, et al. do not disclose a heart valve, which is the subject of the present application and claims. The Examiner does not address this distinction, indeed she assumes that Thorpe, et al. disclose a heart valve on page 3 of the Office Action: "Thorpe discloses a two-part prosthetic heart valve..." Applicants object to the unsupported application of a venous valve to reject claims to a heart valve, especially in an anticipation rejection. As one of skill in the art understands, these devices are not interchangeable. The structural details of venous valves may be quite different than those of heart valves, which are subject to much greater flows, forces and pressures. Even if used in an obviousness rejection, there must be some reason for adapting a venous valve structure to form a heart valve as claimed.

Additionally, claims 38 and 44 each recite a two-part prosthetic heart valve including a leaflet subassembly adapted to mechanically couple to the tissue-engaging base. The Examiner

Serial No.: 10/766,139

Docket No.: PVI-5541DIVCON

Amendment After Final dated November 27, 2006

Responsive to the FINAL Office Action dated September 22, 2006

cites Figures 14-16 of Thorpe, et al. as showing such a two-part structure, and again reiterates in the Interview Summary (albeit with respect to Eberhardt) that a "valve is comprised of many parts, each element alone... may each be considered a "part." This is not, however, what is intended by claiming a two-part prosthetic heart valve. It is clear from the application description that a two-part heart valve has "two detachable components designed to be assembled post-storage" (see brief description of Figure 6). This aspect of the Examiner's rejection, which also applies to her application of other prior art, is unsubstantiated. It is clear from the disclosure what is meant by two parts, and it is not merely two "pieces, fragments, constituents, portions or divisions of a whole" (Examiner's interview summary).

To emphasize the claims to two-part valves as opposed to one part valves in general, the independent claims have been amended to specify that the tissue-engaging base and leaflet subassembly *are separate components* and the leaflet subassembly is adapted to mechanically couple to the tissue-engaging base *at the time of an implant procedure* to form a prosthetic heart valve. Applicants strenuously assert that this does not raise a new issue, and should therefore not be the basis of an Advisory Action. This feature was present in the claims prior to the final Office Action, even if the Examiner did not construe it as such.

Applicants assert that claims 38 and 44 are allowable over Thorpe, et al., which does not disclose a heart valve, does not disclose a two-part heart valve, and does not disclose a two-part heart valve whose parts are adapted to mechanically couple at the time of an implant procedure.

Claim 38 (as amended with the incorporation of claims 40 and 42) also provides that the leaflet subassembly has a support structure comprises an elastic wireform with alternating commissures and cusps for supporting the leaflets. The Examiner points to "commissures (see attachments 91 in fig. 13)" apparently to show the wireform structure. However, these are merely "connection sites" between tissue and a surrounding mesh-like structure, and not a wireform.

Additionally, claim 44 specifies that when the two parts are joined, the three heart valve leaflets are axially spaced from the outflow end of the tubular body such that the heart valve leaflets are not positioned within the tubular body. The Examiner points to the embodiment of

Serial No.: 10/766,139

Docket No.: PVI-5541DIVCON

Amendment After Final dated November 27, 2006

Responsive to the FINAL Office Action dated September 22, 2006

Figures 14-16 in Thorpe, et al. where the leaflets (146 or 89) are axially spaced from the "bottom stage" of the stent structure. This application of a "double stack" stent structure having a first stent coupled at the time of manufacture in series to a second stent is insufficient to anticipate the two-part prosthetic heart valve of claim 44. Applicants respectfully assert that the Examiner appears to be picking and choosing elements of the Thorpe reference to piece together claim 44. What is most apparent is that this is not a two-part structure in the sense of being separate components connectable at the time of an implant procedure.

Accordingly, Applicants assert that claims 38 and 44 are allowable over Thorpe, et al., and therefore their dependent claims are also allowable thereover.

Claim Rejections Based on Cribier

Claims 18-19, 21-22, and 24-25 stand rejected under 35 U.S.C. §102(e) as being anticipated by Cribier (USPN 6,908,481). As mentioned above, claim 20 has been incorporated into claim 18, and therefore this rejection is obviated.

Claim Rejections Based on Eberhardt

Claims 18-22, 24-26, and 44-47 stand rejected under 35 U.S.C. §102(e) as being anticipated by Eberhardt (USPN 6,350,282). The Examiner asserts that Eberhardt discloses an expandable valve "because the base is made of a flexible material, it is capable of being flexed, folded, etc., therefore it is expandable." Applicant respectfully disagrees with the Examiner's characterization of the cited reference. Eberhardt fails to teach or suggest a heart valve that is "expandable from a collapsed state to an expanded state," as recited by Applicant in claim 18. The mere fact that Eberhardt contemplates a flexible material is not sufficient to suggest that Eberhardt has disclosed an expandable valve. The claims do not merely recite "expandable" in a vacuum, instead the collapsed state is sized for delivery through a delivery catheter to a heart valve annulus and the expanded state is sized to contact the heart valve annulus.

Serial No.: 10/766,139

Docket No.: PVI-5541DIVCON

Amendment After Final dated November 27, 2006

Responsive to the FINAL Office Action dated September 22, 2006

In the Interview Summary, the Examiner reiterates that because the separate "part" of the felt cushion 46 is expandable, therefore it could be analogous to the "base" of the claims. Again, Applicants respectfully assert that this interpretation of the words of the claim is unsupported. Not only is the two-part aspect of the heart valve ignored, but the Examiner selects an element of the one-part valve of Eberhardt and postulates that it is "capable of" expansion as in the claims. As indicated above, the two-part character of the heart valves as claimed has been emphasized by the additional language. This is believed to clearly distinguish Eberhardt. For example, claim 18 recites that the tissue-engaging base portion and leaflet subassembly are separate components configured to mechanically connect at the time of an implant procedure, and that the base portion exhibits the aforementioned expanded and contracted states. In contrast, the felt cushion 46 of Eberhardt which forms a part of the sewing cuff 54 is assembled along with the other components of the valve at the time of manufacture. This is not a two-part valve, nor is it a valve with components that have a collapsed state that can pass through a catheter.

Therefore, Eberhardt fails to anticipate claims 18-22, 24-26, and 44-47.

Applicant also wish to point out that certain dependent claims even further distinguish from Eberhardt, et al. In particular, claim 45 specifies that the tissue-engaging base is plastically-expandable from its collapsed state to its expanded state. The Examiner reasons that because the cushion 46 may be torn it is therefore plastically expandable. Applicants respectfully disagree and wish to object to the strained nature of such an interpretation which requires two logical leaps. First, one must agree that an integral sewing ring is the same as a collapsible/expandable tissue-engaging base, which requires the mental exercise of separating the sewing ring from the rest of the valve. Secondly, one must agree that just because a felt sewing ring can be torn that it is plastically expandable. However, the term plastically expandable is not used in isolation, and it means the base is plastically expandable from its collapsed state to its expanded state. Applicants question how a felt sewing ring connected around a one-part heart valve can function in that way.

Serial No.: 10/766,139
Docket No.: PVI-5541DIVCON
Amendment After Final dated November 27, 2006
Responsive to the FINAL Office Action dated September 22, 2006

RECEIVED
CENTRAL FAX CENTER
NOV 27 2006

Claim Rejections Based on Garrison

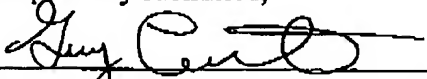
Claims 38-41 and 43 stand rejected under 35 U.S.C. §102(e) as being anticipated by Garrison et al. (USPN 6,425,916). As mentioned above, claim 42 has been incorporated into claim 38, and therefore this rejection is obviated.

New Claims

Applicant has added new claims 50-57 to provide what is believed to be an allowable invention based on the prior art cited. In particular, claim 50 is a combination of claims 38 and 43. The Examiner had stated that the two-part valve shown in Garrison met the elements of claim 43, as explained above in the Interview Summary discussion. However, Applicants disagree that Garrison discloses a plurality of discrete mating connectors on the leaflet subassembly and tissue-engaging base that are configured to join with axial displacement of the leaflet subassembly toward the tissue-engaging base. The Examiner had explained that because the inner part of the two-part valve Garrison must first be axially delivered into the outer part, that this axial displacement element is met. Applicants have added the term "simultaneous" to clarify that the connectors join at the same time of the axial displacement. This is believed to clearly distinguish the necessary axial and radial movements of the inner part of Garrison.

Date: November 27, 2006

Respectfully submitted,


Guy Cumberbatch, Reg. No. 36,114
c/o David Hauser, Reg. No. 42,643
Edwards Lifesciences LLC
Law Department
One Edwards Way
Irvine, California 92614
Telephone: (949) 250-6878
Facsimile: (949) 250-6850
Customer Number: 30452